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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,218	01/18/2001	Markus Haller	P-9417	7371

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EXAMINER

PRIETO, BEATRIZ

ART UNIT	PAPER NUMBER
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2142

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/765,218

Applicant(s)

HALLER ET AL.

Examiner

Prieto Beatriz

Art Unit

2142

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/21/95
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |



DETAILED ACTION

1. This communication is in response to Amendment filed 11/22/04, claims 1, 6, 16, 21, and 30-33 have been amended, claims 1-33 remain pending.

2. Claims 30-31 as amended, fail to comply with C.F.R. 1.75 and M.P.E.P. § 608.01(m). Which states that where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 C.F.R. 1.75 and M.P.E.P. 608.01(i)-(p). Further, § 1.75 (i) states that where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. A remark regarding this “preamble like” structure was made in previous office action. Correction is required.

Examiner for the purposes of examination and/or interpretation has provided a structure. It is respectfully noted that the lack of structure and punctuation opens the claim to various forms of interpretation, correction and/or clarification would also assist in accelerating prosecution of instant application.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 31-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In this case, the following clauses are not clear: (i) “*a software detect exists within one of the IMD exists*”; “*means for determining whether a remote repair available*” and “*in event that the component detect or software detected*”. Correction is required.

5. Quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action may be found in previous office action.

6. Claims 1-11, and 13-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell in view of Nappholz in further view of Kroll et. al.

Regarding claim 1, Snell teaches features of the claimed invention, teachings the system/method of Figs. 1-4, comprising:

an implantable medical device (IMD) (16) implanted with the body of a patient (col 4/lines 10-15);

the IMD being capable of bi-directional communication with a communication module (10) located outside the patient's body (col 7/lines 16-25, 43-56);

a remote communication system (12 of Fig. 1);

a communication system capable supporting bi-directional communication with the remote computer system (col 5/lines 2-36); however Snell is silent with respect to the use of a mobile telephone in the communication system;

Nappholz teaches a system/method related to medical devices, including a cellular telephone (14 of Fig. 5) (col 2/line 66-col 3/line 9, col 5/lines 20-25) communicatively coupled to a communication module and configured to send and receive information (col 2/lines 46-52 and col 4/lines 6-25) and further communicate with a remote computer system (27) (col 4/lines 6-25) via cellular telephone and a communication system (26) (col 4/lines 6-11);

wherein the communication module has means for storing over time collected patient related information "mining patient history" (col 7/lines 8-19, col 8/lines 19-28, 44-48 and col 15/lines 60-65); however Snell and Nappholz are silent with respect to generating invoices;

Kroll teaches a system/method related to generating invoice entity usable with medical devices, specifically, an communication device (12 of Fig. 1) comprising invoice generating entity communicatively couple to a medical device (21 of Fig. 1) (col 3/lines 21-49), the invoice generating device configured to generate an invoice (col 3/lines 62-col 4/line 14, col 5/lines 8-15, 43-68), when communication between the medical device is initiated the communication device invoicing entity (col 4/lines 41-63).

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the suggestions of Snell for monitoring an implantable medical device on a patient, the teachings on Nappholz for the same purpose further including the transmission of data obtained from the monitored device over a cellular network, motivation would be to alert patients condition to a health care provider or facility and provide remedial response if required, including corrective therapy, curative, first-aid, etc). Further, given the same suggestions of the Snell reference, the teachings of Kroll for providing a invoice generation mechanism related to services provided by medical devices would be readily apparent, one would be motivated given the mechanism's transmission, self-contained modularity and add-on capability of Kroll's device, further including the transmission of the formatted invoice and the reception of data

from a remote location over a model, to generate invoices in the Snell's system for transmission to remote locations to base remuneration of services provided based on the actual metered usage of the medical device of the patient.

Regarding claim 2, invoice generation means are incorporated into the communication system, for example communicatively connectable to the medical device for receiving information therein (Kroll: col 3/lines 21-43).

Regarding claim 3, invoice generation means are incorporated into a telephone system included in the communication system (Kroll: col 7/lines 5-16).

Regarding claim 4, system of claim 1, further comprising means for electronically transmitting generated invoices to at least one predetermined location for further processing and billing (Kroll: col 4/lines 7-14).

Regarding claim 5, means (12 of Fig. 1) for calculating the amount of each invoice in accordance with the number, type or frequency of services provided to the patient by the system (Kroll: col 3/line 53-col 4/line 2).

Regarding claim 6, means (12 of Fig. 1) for calculating the amount of each invoice in accordance with the type or identification indicia stored in communication module or IMD (Kroll: col 3/line 53-col 4/line 2).

Regarding claim 7, wherein the remote computer system further comprises means for making a remote diagnostic assessment of the patient's condition on the basis of the information relayed thereto by the IMD or the communication module (Nappholz: col 13/line 47-col 14/line 36).

Regarding claim 8, although Kroll teaches generating an invoice on the basis of the information relayed by the IMD, it does not teach invoice generation in response to a diagnostic assessment;

Official Notice (see MPEP § 2144.03 Reliance on "Well Known" Prior Art) is taken that health care providers and services including health management organization that provide means for quantitatively analyze said providers and services was old and well known in the art. For example and not limited to, the Dang reference (US 5,835,897) discussed as prior art, a medical reimbursement computer system including means (computer implementation) of estimating health care services/consumption

through the use of diagnostic and patient's illness data relationships and computing or calculating the amount of payment to the health provider. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to include means for generating an invoice based on a statistical diagnostic assessment which minimizes variances, motivation would be to automatically further determine an expected cost of treatment based on obtained diagnostic.

Regarding claim 9, wherein the remote computer system further comprises means for remotely executing a remedial response or therapy on the basis of the information relayed thereto by at least one of the IMD and the communication module (col 13/line 47-col 14/line 36.)

Regarding claim 10, this claim is substantially the same as claim 8, thereby same rationale of rejection is applicable.

Regarding claim 11, wherein the communication module is incorporated into the mobile telephone (Nappholz: 14 of Figs. 3-4, col 3/lines 1-65 and col 5/lines 20-25).

Regarding claim 13, wherein the IMD and the communication module communicate with one another using radio-frequency telemetry (Nappholz: col 4/lines 6-9, Fig. 2 and col 5/lines 15-19 also Snell: see 14 of Fig. 1).

Regarding claim 14, wherein the means for generating an invoice is incorporated into a wireless network (Nappholz: col 7/lines 23-27).

Regarding claim 15, generating automatic invoices in response to a patient-initiated (Kroll: col 4/lines 31-63).

Regarding claim 16, this claim is substantially the same as the combined claims 1, and 11, thereby, same rationale of rejection is applicable.

Regarding claims 17-29, these claims are substantially the same as claims 2-13, 14-15, respectively, same rationale of rejection is applicable.

Regarding claim 30, this claim (although presented in a “preamble-like” form) is substantially the same as claim 1, same rationale of rejection is applicable.

Regarding claim 31, the combined teachings of Snell, Nappholz and Kroll as discussed on claim 1, further teach, one mobile telephone (14 of Fig. 5, Nappholz) for use in a system for monitoring the performance of an implantable medical device (IMD) (16 of Fig. 1, Snell) implanted within a body of a patient (Snell, col 4/lines 10-15), wherein the system comprises

the communication module (10 of Fig. 1 of Snell) comprising the mobile telephone capable of receiving information from the IMD (Snell col 7/lines 16-25, 43-56),

means (12 of Fig. 1 of Kroll) for generating an invoice in response to information relating to the IMD being relayed to the mobile telephone (Kroll: col 3/lines 21-49, 62-col 4/line 14, 41-62, col 5/lines 8-15, 43-68),

a remote computer system (12 of Fig. 1 Snell), and

a communication system capable of bi-directional communication with the mobile telephone (Snell col 5/lines 2-36) wherein the communications system is adapted to detect the remote computer system e.g. by means of a transmission protocol involving handshaking (Snell: col 7/lines 43-59).

9. Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over NOLAN et. al. U.S. Patent No. 5,404,877 (Nolan hereafter) in view of Kroll in further view of Snell

Regarding claim 32, Nolan teaches substantial features of the invention, including a system (of Fig. 12) further including:

an implantable medical device (5) (col 3/lines 28-36);

a remote computer system (220 or 260);

the implantable medical device capable of sending/receiving communication with a communication module (240) located external to the patient's body to a remote communication system (220/260) (col 23/lines 65-68 and col 24/lines 14-20);

a cellular/telephonic communicator (240) capable of exchanging information with the communication module (col 23/lines 49-67 and col 24/lines 14-20);

a communication system (Fig. 12) supporting bi-directional communication with the cellular/telephonic communicator (240) external to the patient's body and the remote computer system (260 or 220) (medical device sending to all, i.e. communicator 240 and remote computers (260 & 220) see col 23/lines 65-68 and sending from computer system to medical device see col 24/lines 14-20);

further including a method comprising:

the implantable medical device configured to determine that medical attention should be provided to the patient and provide a warning signal based on said determination (col 2/lines 44-56, col 5/lines 56-60, col 6/lines 60-67, and col 9/lines 10-22, 26-31);

in response to determining that medical attention should be provided sending data from the implantable medical device to the communication module (col 6/lines 60-67, col 9/lines 16-19) for an external remote computer system device;

remotely analyzing the data (col 24/lines 23-26);

determining on the basis of the analyzed data whether remedial action respecting the IMD is required (col 24/line 26-30);

remotely executing the determined remedial action via the communication system which supports communication to the IMD or patient therein (col 24/lines 33-38), however Nolan is silent with regards to invoice generation means in his system, and further the claimed functions performed by the communication module and those performed by the mobile telephone are performed by one element, (i.e. 240) in the Nolan reference;

Kroll teaches a system/method related to generating invoice entity usable with medical devices, specifically, an communication device (12 of Fig. 1) comprising invoice generating entity communicatively couple to a medical device (21 of Fig. 1) (col 3/lines 21-49), the invoice generating device configured to generate an invoice (col 3/lines 62-col 4/line 14, col 5/lines 8-15, 43-68), when communication between the medical device is initiated the communication device invoicing entity (col 4/lines 41-63), however Nolan not Kroll teach detecting a remote computer

Snell teaches wherein the communications system is adapted to detect the remote computer system e.g. by means of a transmission protocol involving handshaking (Snell: col 7/lines 43-59).

It would have been obvious to one ordinary skilled in the art at the time the invention was made given the suggestions of Nolan of a telephonic communicator external to the patient's body, specifically, communicatively coupled to the IMD for sending/sending data thereto, also having mobile phone capabilities for receiving data from the IMD and establishing a telephonic communication with programmable telephone numbers thereby sending messages over a cellular telephone link to remote computer systems. Nolan teaches that these components although not shown individually (microprocessor and sending/receiving circuitry) are also present in the elements 220 and 230. It would be readily apparent to one ordinary skilled in the art that these component are relocatable being either integrated or distributed, e.g. the separation of the telephonic functionalities and the bi-direction communication circuitry would enable multiple patients at home complex building facility each having telephonic

functionality components communicate remotely with their individual health care provider's office via one bi-directional communication circuitry. Furthermore, it would have been obvious to one ordinary skilled in the art at the time the invention was made given the suggestions of Nolan for monitoring an implantable medical device on a patient, the teachings of Snell for doing the same, would be readily apparent and the teachings on Kroll for providing monetary reimbursement for medical services provided, including invoice generation mechanism would be readily apparent, one would be motivated given the mechanism's transmission, self-contained modularity and add-on capability of Kroll's device, further including the transmission of the formatted invoice and the reception of data from a remote location over a model, to generate invoices in the primary reference's system for transmission to remote locations to base remuneration of services provided based on the actual metered usage of the medical device of the patient.

Regarding claim 33, this method claim is substantially the same as claim 32, thereby, same rationale of rejection is applicable.

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Snell-Nappholz in view of Kroll in further view of OTSUKA, Ideal state of high density packing view from wiring technology from human brain to LSI and electronic packaging on circuit boards.

Regarding claim 12, however the above-mentioned references do not teach a mobile telephone comprising a PDA.

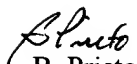
Otsuka teachings the integration of separate electronic communication components, such as a mobile telephone and a PDA. It would have been obvious to one ordinary skilled in the art at the time the invention was made to further integrate separate application, e.g. PDA to the Nappholz system presently integrating the functionalities of a programmable device and a personal computer application configured for receiving/transmitting telemetry data, with cellular telephone technology, for taking the applied reference teaching a step further, using the advantages of LSI technology and further incorporate a PDA, the size of a card, motivation would be to further provide the patient a more user friendly/portable device that existing prior arts as suggested by the Nappholz reference.

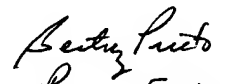
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Beatriz Prieto whose telephone number is (571) 272-3902. The Examiner can normally be reached on Monday-Friday from 6:00 to 3:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's Supervisor, Jack B. Harvey can be reached on (571) 272-3896. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3800/4700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system, status information for published application may be obtained from either Private or Public PAIR, for unpublished application Private PAIR only (see <http://pair-direct.uspto.gov> or the Electronic Business Center at 866-217-9197 (toll-free).


B. Prieto
Primary Examiner
March 16, 2005


Beatriz Prieto
Primary Examiner